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MARK A. LITMAN
MARK A. LITMAN AND ASSOCIATES, P.A.
YORK BUSINESS CENTER, SUITE 205
3209 WEST 76TH ST.
EDINA, MN 55435

EXAMINER	
HAYES, ROBERT CLINTON	

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARK D. SCOTT and JOHN W. EATON

Appeal 2010-002527
Application 09/323,765
Technology Center 1600

Before DONALD E. ADAMS, JEFFREY N. FREDMAN, and STEPHEN WALSH, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This appeal under 35 U.S.C. § 134 involves claims 1-26, 28, and 31 (App. Br. 5). We have jurisdiction under 35 U.S.C. § 6(b).

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF THE CASE

The claims are directed to cellular compositions (claims 1-23, 28, and 31) and a method of producing a non-immunogenic mammalian cell (claims 24-26). Claims 1, 2, and 24 are representative and are reproduced in the "APPENDIX – THE CLAIMS ON APPEAL" of Appellants' Brief.

The rejections presented by the Examiner follow:

1. Claims 2-7, 18-21, 22-25, 28, and 31 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Desai[2] as evidenced by Lin.[3]

2. Claims 1, 4, 8, 10-16, 24, and 26 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Francis.[4]

3. Claims 1-26, 28, and 31 stand rejected under 35 U.S.C § 103(a) as unpatentable over the combination of Desai, Lin, and Francis.

We affirm the rejection of claims 1, 3-12, 15-17, 24, and 26 under 35 U.S.C § 103(a). We reverse the anticipation rejections and the rejection of claims 2, 13, 14, 18-23, 25, 28, and 31 under 35 U.S.C § 103(a).

Anticipation:
The rejection over Desai as evidenced by Lin:

ISSUE

Does the preponderance of evidence on this record support a finding that Desai as evidenced by Lin teaches each and every element as set forth in Appellants' claimed invention?

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[2] Desai et al., US 5,578,442, issued November 26, 1996.
[3] Syr-Yaung Lin et al., *Photochemical Attachment of lac Repressor to Bromodeoxyuridine-Substituted lac Operator by Ultraviolet Radiation*, 71 PROC. NATL. ACAD. SCI. 947-951 (1974).
[4] Francis et al., WO 95/06058, published March 2, 1995.

FINDINGS OF FACT

FF 1. Desai teaches "non-immunogenic cell compositions, as well as methods to produce these compositions, in which non-ionic water soluble polymers (i.e., hydrophilic/biocompatible [polymers] . . .) are covalently attached to viable, *nucleated*, mammalian cells/tissue through free radical polymerization" (Ans. 4). The Examiner asserts that Desai inherently teaches the attachment of polymers to antigenic determinants on the cell surface (*id.*).

FF 2. Desai teaches that

> [T]he polycationic species employed in the practice of the present invention can be further modified with one or more functional groups capable of undergoing free radical polymerization. . . . When cells or tissues are treated with such modified polycationic species, the graft copolymer can be further subjected to free radical polymerization conditions, thereby stabilizing the association of graft copolymer with the cell surface. In addition, the further *crosslinking of the graft copolymer* forms a highly stabilized, immunoprotective coating of water-soluble polymer about the treated cell or tissue.

(Desai, col. 3, ll. 42-56 (emphasis added); *see also id.* at col. 4, ll. 40-54.)

FF 3. Desai teaches that

> The presence of . . . [an acrylate] group on the graft copolymer facilitates polymerization or crosslinking following the absorption of the copolymer onto the cell surface through ionic interactions. *The resultant covalently crosslinked network* is significantly more stable than the ionically attached graft copolymer. Thus the immunoprotective properties conferred upon the cell by absorption of PLL-PEG on its surface are no longer transient as may be expected through an ionic interaction, but are permanent *due to the formation of*

> *intermolecular and intramolecular covalent crosslinks formed with the PLL-PEG.*

(Desai, col. 13, ll. 60-67 (emphasis added).)

FF 4. Desai teaches that "[p]hotopolymerization is the method of choice for covalent crosslinking of the graft copolymer following attachment to the cell surface. . . . This causes *crosslinking of the copolymer on the surface of the cell* resulting in the immunoprotective layer" (Desai, col. 14, ll. 28-41 (emphasis added)).

FF 5. The Examiner relies on Lin "to establish that it is well known in the art that UV-crosslinking forms *covalent bonds* . . . between any molecule" (Ans. 5-6).

ANALYSIS

Appellants contend that Desai fails to teach the requirement in Appellants' claimed invention of the covalent attachment of a compound or polymer to a cell surface (App. Br. 15-16). Contrary to the Examiner's reading of Desai (FF 1) Appellants contend that Desai teaches the "free radical polymerization of components in the composition to each other . . . [not] to a cell" (App. Br. 17). We agree (*see* FF 2-4).

Appellants contend that "Lin provides nothing of substance and does not overcome the reasons given above for the failure of the rejection" (App. Br. 18). We agree.

CONCLUSION OF LAW

The preponderance of evidence on this record fails to support a finding that Desai as evidenced by Lin teaches each and every element as set forth in Appellants' claimed invention.

The rejection of claims 2-7, 18-21, 22-25, 28, and 31 under 35 U.S.C. § 102(e) as being anticipated by Desai as evidenced by Lin is reversed.

The rejection over Francis:

ISSUE

Does the preponderance of evidence on this record support a finding that Francis teaches each and every element as set forth in Appellants' claimed invention?

FINDINGS OF FACT

FF 6. Francis teaches "an improved process for producing polymer:target molecule adducts which are directly covalently linked without any intervening coupling moiety residue from the activating group on the polymer and in which the link between polymer and target moieties is non-immunogenic, non-antigenic, non-toxic and non-biodegradable" (Francis 14: 4-10; *see generally* Ans. 6).

FF 7. Francis teaches that "target molecules . . . include cells or parts thereof, for instance erythrocytes" (Francis 38: 28-29).

FF 8. The Examiner finds that Francis teaches compositions comprising TmPEG covalently attached to the surface of an erythrocyte, "as well as methods to produce these compositions" (Ans. 6).

FF 9. "[T]he TmPEG method as taught by Francis fails to significantly modify RBC and does not yield any protection from immune recognition" (Spec. 30: 26-27).

FF 10. The Examiner finds that Francis teaches the "covalent attachment of other polymers, such as dextran and ficoll . . . and arabinogalactan . . . can be used to improve pharmacological properties of target molecules" (Ans. 6).

ANALYSIS

Appellants' claims require a sufficient amount of hydrophilic, biocompatible, non-immunogenicity providing compound or polymer covalently attached to a cell surface so that recognition of the antigenic determinants on the cell surface is blocked by the covalently bonded compound or polymer (*see, e.g.,* Claim 1).

Appellants contend that their Specification establishes that Francis' method of modifying erythrocytes with TmPEG "did not produce an anti-immunogenic effect" (App. Br. 20; FF 8).

The Examiner failed to establish a factual basis to support a finding that Francis expressly or inherently teaches a composition or method of producing a composition wherein the compound or polymer is covalently attached to a cell surface *so that recognition of the antigenic determinants on the cell surface is blocked* by the covalently bonded compound or polymer as is required by Appellants' claimed invention (*see, e.g.,* Claim 1). In this regard, we recognize Appellants' contention that Francis "fails to provide any motivation for the covalent bonding of compounds to the surface of nuclear or anuclear cells with the provision of an anti-immunogenic effect" (App. Br. 20).

CONCLUSON OF LAW

The preponderance of evidence on this record fails to support a finding that Francis teaches each and every element as set forth in Appellants' claimed invention

The rejection of claims 1, 4, 8, 10-16, 24, and 26 under 35 U.S.C. § 102(b) as being anticipated by Francis is reversed.

Obviousness:

ISSUE

Does the preponderance of evidence on this record support a conclusion of obviousness over Desai, Lin and Francis?

FINDINGS OF FACT

FF 11. The foregoing findings of fact (FF 1 - FF 10) are incorporated by reference (*see* Ans. 7).

FF 12. Desai's method "can be used for rendering non-immunogenic any cell, tissue, organ, or system of organs, and the like, that may be used for transplant or the like" (Desai, col. 6, ll. 15-18; Ans. 8).

FF 13. The Examiner finds that Desai does "not specifically disclose non-immunogenic cellular compositions comprising *anuclear* cells/red blood cells, or methods of producing such" (*id.* at 7).

FF 14. The Examiner finds that Francis does "not teach covalent attachment of other PEG derivatives, or other polymers, to *nuclear* cell surfaces" (*id.*).

FF 15. Francis' Example 14 teaches that "PEG contamination results from its production as a by-product during the polymerization reaction for the manufacture of MPEG" (Francis 83: 13-15).

FF 16. Francis teaches that "the contaminating PEG is, as anticipated, responsible for aggregate formation during the coupling reaction" (Francis 83: 26 - 84:1).

FF 17. Francis teaches that the "[r]eduction of PEG contamination reduces aggregate formation" (Francis 85: 6).

FF 18. Francis teaches that "some coupling moieties provide an immunogenic/antigenic group (e.g., the triazine ring of the cyanuric chloride method" (Francis 10: 32-35).

ANALYSIS

Based on the foregoing facts the Examiner concludes that

> It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to include Francis' red blood cells (RBCs), and alternate methods of covalently attaching other non-immunological polymers to cells . . . in Desai's non-immunological cell compositions, because of the common problems of immunorejection of non-compatible antigenic sites between different species/individuals for both *nuclear* and *anuclear* cells.

(Ans. 8.) We agree.

Appellants provide separate arguments for a number of claim groupings (App. Br. 24-26). Appellants do not, however, separately argue or include claims 28 and 31 in a particular claim grouping. In addition, a number of Appellants' claim groupings include claims that are unrelated to the arguments presented for the particular group. For example, Appellants contend that "[c]laims 2 and 9 shall stand or fall with the patentability of claim 2, reciting a specific degree and test for stability" (App. Br. 24). While claim 2 requires a cellular composition in which at least 25% by number of nuclear cells in said composition remain viable for 96 hours, claim 9 has no requirement of viability. Claim 9 depends from claim 1. Neither claim 1 nor claim 9 recite a specific degree or test for stability and Appellants provide no explanation as to why claim 9 should stand or fall together with claim 2. Accordingly, we have restructured Appellants' claim groupings to more accurately align the claims in each claim grouping with the separate arguments presented by Appellants. As a result we have reviewed the claims as they relate to the following groups:

I. Claims 2, 18-23, and 28 require, *inter alia*, that at least 25% by number of nuclear cells in said composition remain viable for 96 hours.

II. Claims 13 and 25 require, *inter alia*, that the compound or polymer is covalently bound to the antigenic determinant on the cell.

We recognize that claims 19-23 and 28 also contain this limitation, however, these claims were properly grouped with claim 2 from which they depend.

We also note, that Appellants did not include claim 25 in their separate argument regarding the grouping of claims 13 and 19-23 (*see* App. Br. 25 ("[c]laim[s] 13 and 19-23 shall stand or fall with the patentability of claim 13, reciting a specific position of attachment . . . at the determinant sites")). However, since claim 25 requires, *inter alia*, that the compound or polymer is covalently bound to the antigenic determinant on the cell, it would appear that this claim would properly be included with Appellants' separate argument and claim grouping relating to this limitation. Accordingly, we group claim 25 together with claim 13.

III. Claims 14 and 31 require, *inter alia*, that the compound or polymer is covalently bonded to the nuclear cell through a unit derived from reaction of a cyanuric chloride linking group.

We recognize that claims 18 and 28 also contain this limitation, however, these claims were properly grouped with claim 2 from which they depend.

As discussed above, claim 31 was not included in a claim grouping or separately argued. Claim 31, however, contains a similar limitation regarding the covalent bonding of a compound or polymer through a unit derived from reaction of a cyanuric chloride linking group. Accordingly, we

include claim 31 in this grouping. While, claim 28 also includes this limitation, it is properly included with the claims of group VII.

IV. Claims 1, 3, 5-9, 15, 17, 24, and 26 stand or fall together. Claim 24 is representative.

We recognize that this group of claims includes some claims that Appellants group separately, specifically the group of (a) claims 1, 3, 8, 15, 17, 24-26 (App. Br. 24); and (b) claims 5-7 (App. Br. 25). With regard to the "(a)" group, Appellants contend that "[t]he arguments directly above reflect the basic position on this set of claims" (App. Br. 24). With regard to the "(b)" group, Appellants contend that "[p]atentability arguments are otherwise the same as those provided above for claim 1," which is in the (a) group (App. Br. 25). Thus, the arguments presented for each of the (a) and (b) claim groupings are the same.

Nevertheless, we recognize Appellants' contention that the (b) group of claims is "differ[ent] from claim 1 in reciting a *nuclear* cell" (App. Br. 25 (emphasis added)). Stated differently, it would appear that Appellants' justify the separation of the claims into the (a) and (b) groupings based on a limitation in the (b) group claims requiring a "nuclear" cell rather than an "anuclear cell". It is true that claim 5 of group (b) requires a nuclear cell and claim 1 of group (a) requires an anuclear cell. However, in contrast to claim 1, claim 3 of Appellants' group (a) requires a *nuclear* cell. Thus, following Appellants' logic claim 3 should have been grouped with claim 5. In this regard, we recognize that claim 24 does not specify whether the cell is nuclear or anuclear, but is instead open to either type of cell. Nevertheless, Appellants grouped this claim in group (a).

To cut through the ambiguity in Appellants' claim grouping and corresponding arguments we joined Appellants two separate claim groupings into a single group represented by claim 24. In doing so, we will address claim 24 in the context of both a nuclear and an anuclear cell and thereby accommodate Appellants' distinction between the cell types.

In addition, we include claim 9 in this claim grouping because it depends from claim 1 and, as discussed above, Appellants failed to present a persuasive argument as to why it should stand or fall with claim 2.

We have also removed claim 25 from this group for the reasons discussed above.

V. Claim 4 stands or falls alone with regard to the recitation that the composition is free of any by-products from the covalent attachment of the compound or polymer to the cell surface.

VI. Claims 10 and 16 stand or fall together with regard to the requirement that the compound or polymer is a dextran. Claim 10 is representative.

VII. Claim 11 stands or falls alone with regard to the requirement that the compound or polymer is ficoll.

VIII. Claims 12 stands or falls along with regard to the requirement that the compound or polymer is arabinogalactan.

We now address Appellants' contentions with regard to the claim groupings set forth above.

Group I (claims 2, 18-23, and 28):

Claim 2 requires, *inter alia*, that at least 25% by number of nuclear cells in the composition remain viable for 96 hours. Claims 18-23 and 28 depend directly or indirectly from claim 2.

Appellants contend that "the specific degree of viability (which is recited in these claims)" has not been shown to be taught, obvious, enabled or otherwise available from the [combined] teachings of" Desai, Francis, and Lin (App. Br. 24). We agree. The Examiner has failed to identify an evidentiary basis to support a conclusion that the modification of Desai with Francis and Lin will produce a composition of cells, wherein at least 25% by number of nuclear cells in the composition remain viable for 96 hours.

Group II (claims 13 and 25):

Claims 13 and 25 require, *inter alia*, that the linking moieties are covalently bonded to the antigenic determinants on the cell surface. Appellants contend that "[n]either Desai et al. nor Francis has been asserted to specifically show attachment at the determinant sites" (App. Br. 25). We agree. While the Examiner asserts that Desai inherently teaches the covalent attachment of linking moieties to antigenic determinants (FF 1), the Examiner fails to identify an evidentiary basis on this record to support this assertion. Similarly, the Examiner fails to identify a suggestion in Francis of attaching a linking moiety to the antigenic determinant on a cell surface. Accordingly, the Examiner failed to provide an evidentiary basis to support the conclusion of obviousness.

Group III (claims 14 and 31):

Claims 14 and 31 require *inter alia* that the compound or polymer is covalently bonded to the nuclear cell through a unit derived from reaction of a cyanuric chloride linking group on the covalently bonded compound or polymer.

Appellant contends that "[n]either Desai et al. or Francis shows a linking unit derived from a cyanuric chloride reaction product" (App. Br. 25). While we disagree that Francis fails to suggest a cyanuric chloride linking group, Francis teaches that the triazine ring of the cyanuric chloride method provides an immunogenic/antigenic group (FF 18). The Examiner has failed to establish an evidentiary basis to support the conclusion that the use of a cyanuric chloride reaction product would result in, *inter alia*, a non-immunogenic cellular composition as required by Appellants' claims 14, 18, and 31.

Group IV (claims 1, 3, 5-9, 15, 17, 24, and 26):

Claim 24 is representative.

As discussed above, Appellants make a distinction between nuclear and anuclear cells (*see* App. Br. 25). Claim 24 does not restrict the cell to a particular type (e.g., nuclear or anuclear), but is instead inclusive to both. Desai teaches nuclear cells (FF 1). Francis teaches anuclear cells, e.g., erythrocytes (FF 7). Therefore, the combination of Desai, Lin, and Francis suggests the covalent attachment of a compound or polymer to either nuclear or anuclear cells. Accordingly, we are not persuaded by Appellants' contention regarding a distinction between nuclear and anuclear cell types.

We now turn to what Appellants' refer to as "[t]he arguments directly above" (App. Br. 24). These "arguments" are found on pages 22-24 of Appellants' Brief.

We are not persuaded by Appellants' contention regarding the teachings of Desai and Francis taken in isolation (App. Br. 22-23).

We are not persuaded by Appellants' contention regarding Francis' "sole described method" (App. Br. 23). Francis is not limited to its exemplification of TmPEG (*see* FF 8), instead Francis is available for all that it teaches including the covalent attachment of polymers, including, *inter alia*, those polymers identified by the Examiner (FF 10) to improve pharmacological properties of target molecules, such as cells (FF 7).

We are not persuaded by Appellants' contentions regarding the production of a viable cell or aggregation (App. Br. 23). Claim 24 is not limited to a viable cell. Further, to the extent that claim 24 could be read to infer a viable cell, there is no limitation in claim 24 (or either of the claims Appellants' referred to as representative, i.e. claims 1 and 5, (*see* App. Br. 21 and 22)) that relates to a degree of viability (*Cf.* Appellants' claim 2 ("at least 25% by number of nuclear cells in the composition remain viable for 96 hours")). Appellants failed to establish that a cellular composition produced by the combined teachings of Desai, Lin, and Francis would not contain cells that were viable for some time-period.

Further, with regard to Appellants' contention regarding aggregation, Appellants failed to establish that Francis' methodology, as opposed to

conventional methodology[5], fails to produce a non-aggregating composition. Accordingly, while Appellants intimate that "Francis appears to indicate that aggregation still occurs with both his inventive composition and with control compositions (Examples 3 and 4)" (App. Br. 23), Appellants fail to articulate the specific evidentiary basis that supports their contention. In this regard, we note that Francis teaches the "[r]eduction of PEG contamination reduces aggregate formation" (FF 17).

Group V (claim 4):

Appellants contend that "the examples and accompanying descriptions on pages 27-32 show that Francis produces waste bye-products [sic] that damage the cells" (App. Br. 25). We are not persuaded. Appellants do not specifically identify and we do not find a teaching of the production of waste by-products that damage cells on pages 27-32. As for Francis' Examples, we find that Francis' Example 14 speaks of PEG as a by-product of the polymerization reaction (FF 15). However, while Francis teaches that this contaminating PEG is responsible for aggregate formation during the coupling reaction (FF 16), we do not find, and Appellants do not identify a teaching in Francis of this PEG damaging cells. Nevertheless, Francis specifically teaches that this contaminating PEG can be reduced and that doing so will reduce aggregate formation (FF 17). In sum, Appellants failed to provide an evidentiary basis to support their contention.

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[5] Francis teaches that "[c]ommercially available activated PEGs . . . were used to PEGylate recombinant human erythropoietin . . . by the cyanuric chloride (Comparative Example 2), succinimidyl succinate (Comparative Example 3) and phenylchloroformate (MPEG-p-nitrophenylcarbonate) methods (Comparative Example 4).

To the extent that Appellants rely on the arguments presented for claim 24, we are not persuaded for the reasons set forth above.

Group VI (claims 10 and 16):

Claim 10 is representative. Appellants contend that "[n]either Francis nor Desai et al. show a linking unit derived from a cyanuric chloride reaction product" (App. Br. 25). We are not persuaded. Claim 10 does not require a linking unit derived from a cyanuric chloride reaction product.

Appellants also contend that claim 10 recites "a specific blocking group" (App. Br. 25). We agree. Claim 10 requires the compound or polymer to be dextran. However, the Examiner finds that Francis teaches the "covalent attachment of . . . dextran . . . can be used to improve pharmacological properties of target molecules" (FF 10), wherein the target molecule can be a cell (FF 7). Appellants failed to present persuasive evidence or argument to refute the Examiner's finding.

To the extent that Appellants rely on the arguments presented for claim 24, we are not persuaded for the reasons set forth above.

Group VII (claim 11):

Appellants contend that claim 11 recites "a specific blocking group" (App. Br. 25). We agree. Claim 11 requires the compound or polymer to be ficoll. Appellants contend that "[n]either Desai et al. nor Francis show this specific blocking group" (*id.*). We are not persuaded. The Examiner finds that Francis teaches the "covalent attachment of . . . ficoll . . . can be used to improve pharmacological properties of target molecules" (FF 10), wherein

the target molecule can be a cell (FF 7). Appellants failed to present persuasive evidence or argument to refute the Examiner's finding.

To the extent that Appellants rely on the arguments presented for claim 24, we are not persuaded for the reasons set forth above.

Group VIII (claim 12):

Appellants contend that claim 12 recites "a specific blocking group" (App. Br. 25). We agree. Claim 12 requires the compound or polymer to be arabinogalactan. Appellants contend that "[n]either Desai et al. nor Francis show this specific blocking group" (*id.*). We are not persuaded. The Examiner finds that Francis teaches the "covalent attachment of . . . arabinogalactan . . . can be used to improve pharmacological properties of target molecules" (FF 10), wherein the target molecule can be a cell (FF 7). Appellants failed to present persuasive evidence or argument to refute the Examiner's finding.

To the extent that Appellants rely on the arguments presented for claim 24, we are not persuaded for the reasons set forth above.

CONCLUSION OF LAW

The preponderance of evidence on this record supports a conclusion of obviousness with regard to claims 4, 10-12, and 24.

The preponderance of evidence on this record fails to support a conclusion of obviousness with regard to claims 2, 13, 14, 18-23, 25, 28, and 31.

The rejection of claim 24 under 35 U.S.C § 103(a) as unpatentable over the combination of Desai, Lin, and Francis is affirmed. Claims 1, 3, 5-9, 15, 17, and 26 fall together with claim 24.

The rejection of claim 4 under 35 U.S.C § 103(a) as unpatentable over the combination of Desai, Lin, and Francis is affirmed.

The rejection of claim 10 under 35 U.S.C § 103(a) as unpatentable over the combination of Desai, Lin, and Francis is affirmed. Claim 16 falls together with claim 10.

The rejection of claim 11 under 35 U.S.C § 103(a) as unpatentable over the combination of Desai, Lin, and Francis is affirmed.

The rejection of claim 12 under 35 U.S.C § 103(a) as unpatentable over the combination of Desai, Lin, and Francis is affirmed.

The rejection of claims 2, 13, 14, 18-23, 25, 28 and 31 under 35 U.S.C § 103(a) as unpatentable over the combination of Desai, Lin, and Francis is reversed.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

cdc

MARK A. LITMAN
MARK A. LITMAN AND ASSOCIATES, P.A.
YORK BUSINESS CENTER, SUITE 205
3209 WEST 76TH ST.
EDINA, MN 55435